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ATTORNEYS FOR PLAINTIFFS PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, AND ENDO PAR INNOVATION COMPANY, LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC Plaintiffs, v. CIPLA LIMITED and CIPLA USA, INC. Defendants.	Civil Action No. 2:22-cv-2814-MCA-JBC

FIRST AMENDED COMPLAINT

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Par"), for their complaint against Cipla Limited ("Cipla") and Cipla USA, Inc. ("Cipla USA"), hereby allege as follows:

PARTIES

1. Plaintiff Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 6 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States.

2. Plaintiff Par Sterile Products, LLC ("Par Sterile Products") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 6 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Sterile Products develops, manufactures, and markets injectable pharmaceutical products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

3. Plaintiff Endo Par Innovation Company, LLC ("EPIC") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 6 Ram Ridge Road, Chestnut Ridge, New York 10977.

4. Upon information and belief, Defendant Cipla is a corporation organized and existing under the laws of India, having its corporate offices and principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India. Upon information and belief, Cipla is a pharmaceutical company engaged in the research, development, and production of generic pharmaceutical products for distribution and sale throughout the United States, including sales within this judicial district.

5. Upon information and belief, Defendant Cipla USA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059. Upon information and belief, Cipla USA is a wholly owned subsidiary of Cipla Limited, and is engaged in the production, distribution, and sale of generic pharmaceutical products throughout the United States, including sales within this judicial district.

NATURE OF ACTION

6. This is an action for infringement of United States Patent Nos. 9,919,026 (the "'026 Patent"), 9,925,233 (the "'233 Patent"), 9,962,422 (the "'422 Patent"), 9,968,649 (the

"'649 Patent"), 9,974,827 (the "'827 Patent"), 9,981,006 (the "'006 Patent"), 10,010,575 (the "'575 Patent"), and 9,925,234 (the "'234 Patent") (collectively the "Patents-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*.

7. Par also seeks declaratory judgment under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that Cipla and Cipla USA's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products (as detailed below) would directly and indirectly infringe the Patents-in-Suit.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 (patent infringement).

9. This Court has personal jurisdiction over Cipla and Cipla USA.

10. Cipla and Cipla USA have committed – or aided, abetted, planned, contributed to, or participated in the commission of – tortious conduct which will lead to foreseeable harm and injury to Par in the State of New Jersey, and in doing so, Cipla and Cipla USA have purposefully directed its activities at the residents of this forum. The filing of the Cipla ANDA is an act of patent infringement. Upon information and belief, Cipla and Cipla USA intend, upon FDA approval to do so, to produce, distribute, and sell the generic equivalents of Par's VASOSTRICT® 40 units/100 mL and 60 units/100 mL products (as detailed below) that Par accuses of infringement in this matter throughout the United States and in this judicial district.

11. Cipla also regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. Cipla has placed its

products in the stream of commerce for distribution and consumption in New Jersey and derives substantial revenue from selling pharmaceutical products throughout the United States, including in New Jersey. Cipla has also previously submitted to the jurisdiction of this Court and has availed itself of this Court by filing claims in other civil actions.

12. Additionally, Cipla USA has purposely availed itself of the rights and benefits of the State of New Jersey. Cipla USA has engaged in systematic and continuous contacts with the state of New Jersey. Cipla USA has a principal place of business in Warren, New Jersey, and regularly and continuously conducts business within this state. Cipla USA has placed its products in the stream of commerce for distribution and consumption in New Jersey and derives substantial revenue from selling pharmaceutical products throughout the United States, including in New Jersey. Cipla USA has also previously submitted to the jurisdiction of this Court and has availed itself of the Court by filing claims in other civil actions.

13. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) against Cipla because, *inter alia*, Cipla is a foreign corporation and venue is proper in any judicial district having personal jurisdiction, including this District.

14. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) against Cipla USA because, *inter alia*, Cipla USA has a regular and established place of business in Warren, New Jersey and has committed acts of infringement in New Jersey, at least by participating in the submission of Abbreviated New Drug Application No. 216787 in New Jersey.

THE DRUG APPROVAL PROCESS

15. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the U.S. Food and Drug Administration ("FDA"),

typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit to FDA information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and FDA then lists the patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

16. Alternatively, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "reference listed drug" or "branded drug").

17. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify, for instance, that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This is known as a "Paragraph IV Certification."

18. The filer of an ANDA with a Paragraph IV Certification must also provide notice to both the owner of the listed patents and the holder of the NDA for the referenced listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal

bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. *See* 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

19. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to the innovator companies because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to an infringing product without first providing an opportunity for the infringement case to be resolved. Put another way, the innovator company is assured of a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. 355(j)(5)(B)(iii).

FACTUAL BACKGROUND

The Patents-in-Suit

20. On March 20, 2018, the PTO duly and legally issued the '026 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '026 Patent is attached as Exhibit A. Par Pharmaceutical owns the '026 Patent.

21. On March 27, 2018, the PTO duly and legally issued the '233 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '233 Patent is attached as Exhibit B. Par Pharmaceutical owns the '233 Patent.

22. On May 8, 2018, the PTO duly and legally issued the '422 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as

assignee. A true and correct copy of the '422 Patent is attached as Exhibit C. Par Pharmaceutical owns the '422 Patent.

23. On May 15, 2018, the PTO duly and legally issued the '649 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '649 Patent is attached as Exhibit D. Par Pharmaceutical owns the '649 Patent.

24. On May 22, 2018, the PTO duly and legally issued the '827 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '827 Patent is attached as Exhibit E. Par Pharmaceutical owns the '827 Patent.

25. On May 29, 2018, the PTO duly and legally issued the '006 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '006 Patent is attached as Exhibit F. Par Pharmaceutical owns the '006 Patent.

26. On July 3, 2018, the PTO duly and legally issued the '575 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '575 Patent is attached as Exhibit G. Par Pharmaceutical owns the '575 Patent.

27. On March 27, 2018, the PTO duly and legally issued the '234 Patent, entitled "Vasopressin Formulations For Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. On July 5, 2022, the PTO issued a Certificate of Correction that corrected an error in the language of claim 1 of the '234 Patent. A true and correct copy of the

'234 Patent, including the Certificate of Correction, is attached as Exhibit H. Par Pharmaceutical owns the '234 patent.

28. EPIC is the exclusive licensee of the Patents-in-Suit.

VASOSTRICT®

29. Vasopressin, the active ingredient in VASOSTRICT (described below), is a polypeptide hormone that causes contraction of vascular and other smooth muscle cells. VASOSTRICT is a lifesaving drug often used when the blood pressure of a critical care patient drops precipitously.

30. On September 25, 2012, JHP Pharmaceuticals ("JHP") submitted NDA No. 204485, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), seeking FDA approval for a vasopressin injection product to increase blood pressure in adults with vasodilatory shock. On April 17, 2014, the FDA approved NDA 204485 as the first FDA-approved vasopressin injection product for use in a clinical setting in the United States.

31. On February 20, 2014, Par Pharmaceutical Companies, Inc. acquired JHP Pharmaceuticals, LLC. On February 26, 2014, JHP Pharmaceuticals, LLC changed its name to Par Sterile Products, LLC.

32. Par Sterile Products is the holder of NDA 204485, including all supplements thereto, for VASOSTRICT.

33. Par Sterile Products submitted supplemental NDAs, including for approval of 40 units/100 mL and 60 units/100 mL presentations of VASOSTRICT ("VASOSTRICT Premixed Products"), which the FDA approved on April 15, 2020.

34. Par timely submitted information regarding the Patents-in-Suit for listing in the "Orange Book" with respect to the VASOSTRICT Premixed Products, pursuant to 21

U.S.C. § 355(b)(1) and (c)(2). The FDA thereafter listed the Patents-in-Suit in the Orange Book with respect to those products, pursuant to 21 C.F.R. § 314.53(e).

35. VASOSTRICT is FDA-approved as indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite the provision of fluids and catecholamines. Par markets and sells its VASOSTRICT products to hospitals, both directly and via group purchasing organizations and wholesalers.

Cipla's Infringing Vasopressin Injection Products

36. Upon information and belief, on or before February 28, 2022, Cipla, with the active involvement of Cipla USA, submitted ANDA No. 216787 (the "Cipla ANDA") pursuant to 35 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, importation, use, marketing, and sale of proposed generic Vasopressin Injection USP, 40 units/100 mL (0.4 units/mL) and 60 units/100mL (0.6 units/mL) products, referencing Par's VASOSTRICT Premixed Products as the reference listed drug (the "Proposed ANDA Products").

37. On or about March 30, 2022, Cipla sent Par a notice stating that Cipla had submitted the Cipla ANDA seeking approval to manufacture, import, use, market, and sell the Proposed ANDA Products prior to the expiration of the Patents-in-Suit (the "Paragraph IV Notice").

38. Par first received the Paragraph IV Notice on March 31, 2022.

39. The Paragraph IV Notice advised that the Cipla ANDA includes Paragraph IV Certifications stating that it is Cipla's opinion that the Patents-in-Suit are invalid and not infringed by the Proposed ANDA Products. The Paragraph IV Notice included an Offer of Confidential Access to the Cipla ANDA pursuant to 21 U.S.C. § 355(j)(5)(C).

40. On April 8, Par requested confidential access to the Cipla ANDA pursuant to the terms of Cipla's Offer of Confidential Access, subject to Par's proposed edits, which were intended to provide Par with access to the appropriate materials and to make the restrictions consistent with those under standard protective orders in ANDA litigations.

41. Thereafter, the parties negotiated the provisions of the Offer of Confidential Access. Cipla finally agreed to an Offer of Confidential Access and provided a copy of the Cipla ANDA to Par on May 9, 2022, only four business days before expiration of the 45-day period set forth in the Hatch-Waxman Act for filing of a complaint for infringement thereunder.

42. Cipla's late production of the Cipla ANDA to Par has prevented Par from having a full and fair opportunity to complete its review of critical information relevant to the design, operation, and characteristics of the Proposed ANDA Products. Nevertheless, upon information and belief, based on Par's investigation thus far, and subject to Par's ongoing investigation, submission of the Cipla ANDA to the FDA and any commercial manufacture or sale by Cipla and Cipla USA of the Proposed ANDA Products has infringed and will infringe the Patents-in-Suit, as detailed below.

COUNT I
INFRINGEMENT OF THE '026 PATENT

43. Par incorporates each of the preceding paragraphs as if fully set forth herein.

44. The submission of the Cipla ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the Proposed ANDA Products prior to the

expiration of the '026 Patent, constitutes infringement by Cipla and Cipla USA of the '026 Patent under 35 U.S.C. § 271(e)(2)(A).

45. Moreover, any commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products by Cipla and/or Cipla USA before expiration of the '026 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '026 Patent under 35 U.S.C. §§ 271(a)-(c).

46. In particular, and among other things, the commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to such infringement of at least claim 1 of the '026 Patent, which recites as follows:

> Claim 1: A pharmaceutical composition for intravenous administration comprising, in a unit dosage form:
> from about 0.1 μg/mL to about 2 μg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> impurities that are present in an amount of 0.9% to 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;
> about 5% dextrose;
> and from about 1 mM to about 10 mM acetate buffer, and wherein the unit dosage form has a pH of 3.6 to 3.9;
> and wherein the unit dosage form is suitable for administration at a concentration of from about 0.1 μg/ml to about 2 μg/ml of vasopressin or the pharmaceutically acceptable salt thereof.

47. The Proposed ANDA Products satisfy each of the recited elements of the pharmaceutical composition recited in at least claim 1, either literally or under the doctrine of equivalents, such that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products by Cipla and Cipla USA would infringe at least claim 1 of the '026 Patent.

48. If the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would induce physicians and other medical professionals to use and administer the Proposed ANDA Products and would contribute to such use and administration in a manner that directly infringes at least claim 1 of the '026 Patent.

49. Cipla and Cipla USA would knowingly, intentionally, and actively induce, encourage, and contribute to that infringement, by virtue of the labeling to be included for the Proposed ANDA Products and Cipla's and Cipla USA's marketing of the products, including marketing it as a generic substitute for the VASOSTRICT Premixed Products to be used and administered in the same manner as the VASOSTRICT Premixed Products.

50. Cipla and Cipla USA would induce and contribute to that infringement with full knowledge of the '026 Patent, knowing that the conduct it was encouraging and contributing to would constitute infringement of the '026 Patent.

51. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '026 Patent would cause Par to suffer immediate and irreparable harm.

52. Cipla's and Cipla USA's infringement of the '026 Patent is willful.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '026 PATENT

53. Par incorporates each of the preceding paragraphs as if fully set forth herein.

54. For the reasons explained in Count I above, if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead

to direct infringement, contributory infringement, and/or active inducement of infringement of at least claim 1 of the '026 Patent under 35 U.S.C. §§ 271(a)-(c).

55. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '026 Patent would cause Par to suffer immediate and irreparable harm.

56. Cipla's and Cipla USA's infringement of the '026 Patent would be willful.

57. Par understands based on the Paragraph IV Notice that Cipla and Cipla USA would dispute that they would be liable for such infringement. Accordingly, there is a definite and concrete controversy between Par and Cipla and Cipla USA as to whether Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the '026 Patent. Par is entitled to a declaratory judgment that it would.

COUNT III
INFRINGEMENT OF THE '233 PATENT

58. Par incorporates each of the preceding paragraphs as if fully set forth herein.

59. The submission of the Cipla ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the Proposed ANDA Products prior to the expiration of the '233 Patent, constitutes infringement by Cipla and Cipla USA of the '233 Patent under 35 U.S.C. § 271(e)(2)(A).

60. Moreover, any commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products by Cipla and Cipla USA before expiration of the '233 Patent would lead to direct infringement, contributory

infringement, and/or active inducement of infringement of the '233 Patent under 35 U.S.C. §§ 271(a)-(c).

61. In particular, and among other things, the commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to such infringement of at least claim 1 of the '233 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> a) storing at 5° C. for at least about one month a pharmaceutical composition for intravenous administration comprising, in a unit dosage form: i) from about 0.1 μg/mL to about 2 μg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) dextrose; and iii) from about 1 mM to about 10 mM acetate buffer, wherein the unit dosage form has a pH of 3.6 to 3.9,
>
> wherein the pharmaceutical composition exhibits no more than about 1% degradation of vasopressin or the pharmaceutically-acceptable salt thereof after the storage at 5° C. for about one month; and
>
> b) administering to the human the pharmaceutical composition, wherein the pharmaceutical composition comprises from about 0.1 μg/mL to about 2 μg/mL of vasopressin or the pharmaceutically acceptable salt thereof;
>
> wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive.

62. The Proposed ANDA Products satisfy each of the recited elements of the pharmaceutical composition recited in at least claim 1, either literally or under the doctrine of equivalents, and if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would induce physicians and other medical professionals to use and administer the Proposed ANDA Products and would contribute to such use and administration in a manner that directly infringes at least claim 1 of the '233 Patent.

63. Cipla and Cipla USA would knowingly, intentionally, and actively induce, encourage, and contribute to that infringement, by virtue of the labeling to be included for the Proposed ANDA Products and Cipla's and Cipla USA's marketing of the products, including marketing it as a generic substitute for the VASOSTRICT Premixed Products to be used and administered in the same manner as the VASOSTRICT Premixed Products.

64. Cipla and Cipla USA would induce and contribute to that infringement with full knowledge of the '233 Patent, knowing that the conduct it was encouraging and contributing to would constitute infringement of the '233 Patent.

65. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '233 Patent would cause Par to suffer immediate and irreparable harm.

66. Cipla's and Cipla USA's infringement of the '233 Patent is willful.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '233 PATENT

67. Par incorporates each of the preceding paragraphs as if fully set forth herein.

68. For the reasons explained in Count III above, if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to direct infringement, contributory infringement, and/or active inducement of infringement of at least claim 1 of the '233 Patent under 35 U.S.C. §§ 271(a)-(c).

69. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '233 Patent would cause Par to suffer immediate and irreparable harm.

70. Cipla's and Cipla USA's infringement of the '233 Patent would be willful.

71. Par understands based on the Paragraph IV Notice that Cipla and Cipla USA would dispute that they would be liable for such infringement. Accordingly, there is a definite and concrete controversy between Par and Cipla and Cipla USA as to whether Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the '233 Patent. Par is entitled to a declaratory judgment that it would.

COUNT V
INFRINGEMENT OF THE '422 PATENT

72. Par incorporates each of the preceding paragraphs as if fully set forth herein.

73. The submission of the Cipla ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the Proposed ANDA Products prior to the expiration of the '422 Patent, constitutes infringement by Cipla and Cipla USA of the '422 Patent under 35 U.S.C. § 271(e)(2)(A).

74. Moreover, any commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products by Cipla and Cipla USA before expiration of the '422 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '422 Patent under 35 U.S.C. §§ 271(a)-(c).

75. In particular, and among other things, the commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to such infringement of at least claim 1 of the '422 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> providing a pharmaceutical composition that comprises, in a unit dosage form: i) from about 0.1 μg/mL to about 2 μg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) dextrose; iii) from about 1 mM to about 10 mM acetate buffer; and iv) a plurality of peptides in an amount of about 1.5% to about 12.9%, wherein the unit dosage form has a pH of 3.6 to 3.9;
>
> storing the unit dosage form for at least about 24 hours at a concentration of from about 0.1 μg/ml to about 2 μg/ml of vasopressin or a pharmaceutically-acceptable salt thereof; and
>
> after the storing, intravenously administering the unit dosage form to the human;
>
> wherein:
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,
>
> wherein the unit dosage form that is administered to the human comprises from about 0.1 μg/mL to about 2 μg/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and
>
> the human is hypotensive.

76. The Proposed ANDA Products satisfy each of the recited elements of the pharmaceutical composition recited in at least claim 1, either literally or under the doctrine of equivalents, and if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would induce physicians and other medical professionals to use and administer the Proposed ANDA Products and would contribute to such use and administration in a manner that directly infringes at least claim 1 of the '422 Patent.

77. Cipla and Cipla USA would knowingly, intentionally, and actively induce, encourage, and contribute to that infringement, by virtue of the labeling to be included for the Proposed ANDA Products and Cipla's and Cipla USA's marketing of the products, including marketing it as a generic substitute for the VASOSTRICT Premixed Products to be used and administered in the same manner as the VASOSTRICT Premixed Products.

78. Cipla and Cipla USA would induce and contribute to that infringement with full knowledge of the '422 Patent, knowing that the conduct it was encouraging and contributing to would constitute infringement of the '422 Patent.

79. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '422 Patent would cause Par to suffer immediate and irreparable harm.

80. Cipla's and Cipla USA's infringement of the '422 Patent is willful.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '422 PATENT

81. Par incorporates each of the preceding paragraphs as if fully set forth herein.

82. For the reasons explained in Count V above, if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to direct infringement, contributory infringement, and/or active inducement of infringement of at least claim 1 of the '422 Patent under 35 U.S.C. §§ 271(a)-(c).

83. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '422 Patent would cause Par to suffer immediate and irreparable harm.

84. Cipla's and Cipla USA's infringement of the '422 Patent would be willful.

85. Par understands based on the Paragraph IV Notice that Cipla and Cipla USA would dispute that they would be liable for such infringement. Accordingly, there is a definite and concrete controversy between Par and Cipla and Cipla USA as to whether Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the '422 Patent. Par is entitled to a declaratory judgment that it would.

COUNT VII
INFRINGEMENT OF THE '649 PATENT

86. Par incorporates each of the preceding paragraphs as if fully set forth herein.

87. The submission of the Cipla ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the Proposed ANDA Products prior to the expiration of the '649 Patent, constitutes infringement by Cipla and Cipla USA of the '649 Patent under 35 U.S.C. § 271(e)(2)(A).

88. Moreover, any commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products by Cipla and Cipla USA before expiration of the '649 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '649 Patent under 35 U.S.C. §§ 271(a)-(c).

89. In particular, and among other things, the commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to such infringement of at least claim 1 of the '649 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> providing a unit dosage form, wherein the unit dosage form comprises from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof,
>
> wherein the unit dosage form has a pH of 3.6 to 3.9;
>
> the unit dosage form further comprises impurities that are present in an amount of 0.9%-1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, dextrose, and from about 1 mM to about 10 mM acetate buffer;

storing the unit dosage form for at least about 24 hours at from about 0.1 units/ml to about 1 unit/ml vasopressin or a pharmaceutically-acceptable salt thereof;

after the storing, intravenously administering the unit dosage form to the human;

wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,

wherein the unit dosage form that is administered to the human comprises from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and

the human is hypotensive.

90. The Proposed ANDA Products satisfy each of the recited elements of the unit dosage form recited in at least claim 1, either literally or under the doctrine of equivalents, and if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would induce physicians and other medical professionals to use and administer the Proposed ANDA Products and would contribute to such use and administration in a manner that directly infringes at least claim 1 of the '649 Patent.

91. Cipla and Cipla USA would knowingly, intentionally, and actively induce, encourage, and contribute to that infringement, by virtue of the labeling to be included for the Proposed ANDA Products and Cipla's and Cipla USA's marketing of the products, including marketing it as a generic substitute for the VASOSTRICT Premixed Products to be used and administered in the same manner as the VASOSTRICT Premixed Products.

92. Cipla and Cipla USA would induce and contribute to that infringement with full knowledge of the '649 Patent, knowing that the conduct it was encouraging and contributing to would constitute infringement of the '649 Patent.

93. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '649 Patent would cause Par to suffer immediate and irreparable harm.

94. Cipla's and Cipla USA's infringement of the '649 Patent is willful.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '649 PATENT

95. Par incorporates each of the preceding paragraphs as if fully set forth herein.

96. For the reasons explained in Count VII above, if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to direct infringement, contributory infringement, and/or active inducement of infringement of at least claim 1 of the '649 Patent under 35 U.S.C. §§ 271(a)-(c).

97. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '649 Patent would cause Par to suffer immediate and irreparable harm.

98. Cipla's and Cipla USA's infringement of the '649 Patent would be willful.

99. Par understands based on the Paragraph IV Notice that Cipla and Cipla USA would dispute that they would be liable for such infringement. Accordingly, there is a definite and concrete controversy between Par and Cipla and Cipla USA as to whether Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the '649 Patent. Par is entitled to a declaratory judgment that it would.

COUNT IX
INFRINGEMENT OF THE '827 PATENT

100. Par incorporates each of the preceding paragraphs as if fully set forth herein.

101. The submission of the Cipla ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the Proposed ANDA Products prior to the expiration of the '827 Patent, constitutes infringement by Cipla and Cipla USA of the '827 Patent under 35 U.S.C. § 271(e)(2)(A).

102. Moreover, any commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products by Cipla and Cipla USA before expiration of the '827 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '827 Patent under 35 U.S.C. §§ 271(a)-(c).

103. In particular, and among other things, the commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to such infringement of at least claim 1 of the '827 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> a) providing a pharmaceutical composition comprising, in a unit dosage form: i) from about 0.1 μg/mL to about 2 μg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) dextrose; and iii) from about 1 mM to about 10 mM acetate buffer; wherein the unit dosage form has a pH of 3.6 to 3.9;
>
> b) storing the unit dosage form at 2-8° C. for at least about 24 hours; and
>
> c) after the storing, intravenously administering the unit dosage form to the human, wherein the unit dosage form comprises from about 0.1 μg/mL to about 2 μg/mL of vasopressin or the pharmaceutically-acceptable salt thereof;
>
> wherein:
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive.

104. The Proposed ANDA Products satisfy each of the recited elements of the pharmaceutical composition recited in at least claim 1, either literally or under the doctrine of equivalents, and if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would induce physicians and other medical professionals to use and administer the Proposed ANDA Products and would contribute to such use and administration in a manner that directly infringes at least claim 1 of the '827 Patent.

105. Cipla and Cipla USA would knowingly, intentionally, and actively induce, encourage, and contribute to that infringement, by virtue of the labeling to be included for the Proposed ANDA Products and Cipla's and Cipla USA's marketing of the products, including marketing it as a generic substitute for the VASOSTRICT Premixed Products to be used and administered in the same manner as the VASOSTRICT Premixed Products.

106. Cipla and Cipla USA would induce and contribute to that infringement with full knowledge of the '827 Patent, knowing that the conduct it was encouraging and contributing to would constitute infringement of the '827 Patent.

107. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '827 Patent would cause Par to suffer immediate and irreparable harm.

108. Cipla's and Cipla USA's infringement of the '827 Patent is willful.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '827 PATENT

109. Par incorporates each of the preceding paragraphs as if fully set forth herein.

110. For the reasons explained in Count IX above, if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for

sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to direct infringement, contributory infringement, and/or active inducement of infringement of at least claim 1 of the '827 Patent under 35 U.S.C. §§ 271(a)-(c).

111. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '827 Patent would cause Par to suffer immediate and irreparable harm.

112. Cipla's and Cipla USA's infringement of the '827 Patent would be willful.

113. Par understands based on the Paragraph IV Notice that Cipla and Cipla USA would dispute that they would be liable for such infringement. Accordingly, there is a definite and concrete controversy between Par and Cipla and Cipla USA as to whether Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the '827 Patent. Par is entitled to a declaratory judgment that it would.

COUNT XI
INFRINGEMENT OF THE '006 PATENT

114. Par incorporates each of the preceding paragraphs as if fully set forth herein.

115. The submission of the Cipla ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the Proposed ANDA Products prior to the expiration of the '006 Patent, constitutes infringement by Cipla and Cipla USA of the '006 Patent under 35 U.S.C. § 271(e)(2)(A).

116. Moreover, any commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products by Cipla and Cipla USA before expiration of the '006 Patent would lead to direct infringement, contributory

infringement, and/or active inducement of infringement of the '006 Patent under 35 U.S.C. §§ 271(a)-(c).

117. In particular, and among other things, the commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to such infringement of at least claim 1 of the '006 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> providing a pharmaceutical composition that comprises, in a unit dosage form i) from about 0.1 μg/mL to about 2 μg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) dextrose; iii) from about 1 mM to about 10 mM acetate buffer; and iv) SEQ ID NO.: 2, wherein the unit dosage form has a pH of 3.6 to 3.9;
>
> storing the unit dosage form for at least about 24 hours at a concentration from about 0.1 μg/ml to about 2 μg/mL vasopressin or a pharmaceutically-acceptable salt thereof; and
>
> after the storing, intravenously administering the unit dosage form to the human;
>
> wherein:
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,
>
> wherein the vasopressin or the pharmaceutically-acceptable salt thereof and SEQ ID NO.:2 are present in the unit dosage form at a ratio of about 1000: about 1 to about 30: about 1,
>
> wherein the unit dosage form that is administered to the human comprises from about 0.1μg/mL to about 2 μg/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and
>
> the human is hypotensive.

118. The Proposed ANDA Products satisfy each of the recited elements of the pharmaceutical composition recited in at least claim 1, either literally or under the doctrine of equivalents, and if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would induce physicians and other medical professionals

to use and administer the Proposed ANDA Products and would contribute to such use and administration in a manner that directly infringes at least claim 1 of the ’006 Patent.

119. Cipla and Cipla USA would knowingly, intentionally, and actively induce, encourage, and contribute to that infringement, by virtue of the labeling to be included for the Proposed ANDA Products and Cipla’s and Cipla USA’s marketing of the products, including marketing it as a generic substitute for the VASOSTRICT Premixed Products to be used and administered in the same manner as the VASOSTRICT Premixed Products.

120. Cipla and Cipla USA would induce and contribute to that infringement with full knowledge of the ’006 Patent, knowing that the conduct it was encouraging and contributing to would constitute infringement of the ’006 Patent.

121. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the ’006 Patent would cause Par to suffer immediate and irreparable harm.

122. Cipla’s and Cipla USA’s infringement of the ’006 Patent is willful.

COUNT XII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’006 PATENT

123. Par incorporates each of the preceding paragraphs as if fully set forth herein.

124. For the reasons explained in Count XI above, if the FDA were to approve the Cipla ANDA, Cipla’s and Cipla USA’s commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to direct infringement, contributory infringement, and/or active inducement of infringement of at least claim 1 of the ’006 Patent under 35 U.S.C. §§ 271(a)-(c).

125. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the ’006 Patent would cause Par to suffer immediate and irreparable harm.

126. Cipla's and Cipla USA's infringement of the '006 Patent would be willful.

127. Par understands based on the Paragraph IV Notice that Cipla and Cipla USA would dispute that they would be liable for such infringement. Accordingly, there is a definite and concrete controversy between Par and Cipla and Cipla USA as to whether Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the '006 Patent. Par is entitled to a declaratory judgment that it would.

COUNT XIII
INFRINGEMENT OF THE '575 PATENT

128. Par incorporates each of the preceding paragraphs as if fully set forth herein.

129. The submission of the Cipla ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the Proposed ANDA Products prior to the expiration of the '575 Patent, constitutes infringement by Cipla and Cipla USA of the '575 Patent under 35 U.S.C. § 271(e)(2)(A).

130. Moreover, any commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products by Cipla and Cipla USA before expiration of the '575 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '575 Patent under 35 U.S.C. §§ 271(a)-(c).

131. In particular, and among other things, the commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA

Products would lead to such infringement of at least claim 1 of the '575 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> providing a pharmaceutical composition that comprises, in a unit dosage form: i) from about 0.1 μg/mL to about 2 μg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) dextrose; iii) from about 1 mM to about 10 mM acetate buffer; and iv) SEQ ID NO.: 3, wherein the unit dosage form has a pH of 3.6 to 3.9;
>
> storing the unit dosage form for at least about 24 hours at a concentration of from about 0.1 ug/ml to about 2 μg/ml of vasopressin or a pharmaceutically-acceptable salt thereof; and
>
> after the storing, intravenously administering the unit dosage form to the human;
>
> wherein:
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,
>
> wherein the vasopressin or the pharmaceutically-acceptable salt thereof and SEQ ID NO.:3 are present in the unit dosage form at a ratio of about 1000:about 1 to about 90:about 1,
>
> wherein the unit dosage form that is administered to the human comprises from about 0.1 μg/mL to about 2 μg/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and
>
> the human is hypotensive.

132. The Proposed ANDA Products satisfy each of the recited elements of the pharmaceutical composition recited in at least claim 1, either literally or under the doctrine of equivalents, and if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would induce physicians and other medical professionals to use and administer the Proposed ANDA Products and would contribute to such use and administration in a manner that directly infringes at least claim 1 of the '575 Patent.

133. Cipla and Cipla USA would knowingly, intentionally, and actively induce, encourage, and contribute to that infringement, by virtue of the labeling to be included for the

Proposed ANDA Products and Cipla's and Cipla USA's marketing of the products, including marketing it as a generic substitute for the VASOSTRICT Premixed Products to be used and administered in the same manner as the VASOSTRICT Premixed Products.

134. Cipla and Cipla USA would induce and contribute to that infringement with full knowledge of the '575 Patent, knowing that the conduct it was encouraging and contributing to would constitute infringement of the '575 Patent.

135. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '575 Patent would cause Par to suffer immediate and irreparable harm.

136. Cipla's and Cipla USA's infringement of the '575 Patent is willful.

COUNT XIV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '575 PATENT

137. Par incorporates each of the preceding paragraphs as if fully set forth herein.

138. For the reasons explained in Count XIII above, if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to direct infringement, contributory infringement, and/or active inducement of infringement of at least claim 1 of the '575 Patent under 35 U.S.C. §§ 271(a)-(c).

139. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '575 Patent would cause Par to suffer immediate and irreparable harm.

140. Cipla's and Cipla USA's infringement of the '575 Patent would be willful.

141. Par understands based on the Paragraph IV Notice that Cipla and Cipla USA would dispute that they would be liable for such infringement. Accordingly, there is a definite and concrete controversy between Par and Cipla and Cipla USA as to whether Cipla's

and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the '575 Patent. Par is entitled to a declaratory judgment that it would.

COUNT XV
INFRINGEMENT OF THE '234 PATENT

142. Par incorporates each of the preceding paragraphs as if fully set forth herein.

143. The submission of the Cipla ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the Proposed ANDA Products prior to the expiration of the '234 Patent, constitutes infringement by Cipla and Cipla USA of the '234 Patent under 35 U.S.C. § 271(e)(2)(A).

144. Moreover, any commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products by Cipla and Cipla USA before expiration of the '234 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '234 Patent under 35 U.S.C. §§ 271(a)-(c).

145. In particular, and among other things, the commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to such infringement of at least claim 1 of the '234 Patent, which as corrected, recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a unit dosage form for intravenous administration, wherein the unit dosage form comprises:
> i) from about 0.1 units/mL to about 1 unit/mL of vasopressin or a pharmaceutically-acceptable salt thereof;

ii) from about 1 mM to about 10 mM acetate buffer;
iii) no more than about 0-2% vasopressin degradation products;
iv) about 5% dextrose; and
v) water; and

b) storing the unit dosage form for at least about 24 hours at a concentration from about 0.1 units/mL to about 1 unit/mL of vasopressin or a pharmaceutically-acceptable salt thereof; and

c) after the storing, administering the unit dosage form to the human by intravenous administration, wherein the unit dosage form comprises from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; wherein:

the unit dosage form has a pH of 3.6 to 3.9; the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and the human is hypotensive.

146. The Proposed ANDA Products satisfy each of the recited elements of the pharmaceutical composition recited in at least claim 1, either literally or under the doctrine of equivalents, and if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would induce physicians and other medical professionals to use and administer the Proposed ANDA Products and would contribute to such use and administration in a manner that directly infringes at least claim 1 of the '234 Patent.

147. Cipla and Cipla USA would knowingly, intentionally, and actively induce, encourage, and contribute to that infringement, by virtue of the labeling to be included for the Proposed ANDA Products and Cipla's and Cipla USA's marketing of the products, including marketing it as a generic substitute for the VASOSTRICT Premixed Products to be used and administered in the same manner as the VASOSTRICT Premixed Products.

148. Cipla and Cipla USA would induce and contribute to that infringement with full knowledge of the '234 Patent, knowing that the conduct it was encouraging and contributing to would constitute infringement of the '234 Patent.

149. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '234 Patent would cause Par to suffer immediate and irreparable harm.

150. Cipla's and Cipla USA's infringement of the '234 Patent is willful.

COUNT XII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '234 PATENT

151. Par incorporates each of the preceding paragraphs as if fully set forth herein.

152. For the reasons explained in Count XI above, if the FDA were to approve the Cipla ANDA, Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would lead to direct infringement, contributory infringement, and/or active inducement of infringement of at least claim 1 of the '234 Patent under 35 U.S.C. §§ 271(a)-(c).

153. Any launch by Cipla or Cipla USA of the Proposed ANDA Products before expiration of the '234 Patent would cause Par to suffer immediate and irreparable harm.

154. Cipla's and Cipla USA's infringement of the '234 Patent would be willful.

155. Par understands based on the Paragraph IV Notice that Cipla and Cipla USA would dispute that they would be liable for such infringement. Accordingly, there is a definite and concrete controversy between Par and Cipla and Cipla USA as to whether Cipla's and Cipla USA's commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the '234 Patent. Par is entitled to a declaratory judgment that it would.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Cipla and Cipla USA have infringed the ’026 Patent, and a declaration that Cipla’s and Cipla USA’s commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the ’026 Patent;

B. A judgment that Cipla and Cipla USA have infringed the ’233 Patent, and a declaration that Cipla’s and Cipla USA’s commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the ’233 Patent;

C. A judgment that Cipla and Cipla USA have infringed the ’422 Patent, and a declaration that Cipla’s and Cipla USA’s commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the ’422 Patent;

D. A judgment that Cipla and Cipla USA have infringed the ’649 Patent, and a declaration that Cipla’s and Cipla USA’s commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the ’649 Patent;

E. A judgment that Cipla and Cipla USA have infringed the ’827 Patent, and a declaration that Cipla’s and Cipla USA’s commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the ’827 Patent;

F. A judgment that Cipla and Cipla USA have infringed the ’006 Patent, and a declaration that Cipla’s and Cipla USA’s commercial manufacture, use, marketing, offer for sale,

sale, and/or importation into the United States of the Proposed ANDA Products would infringe the ’006 Patent;

G. A judgment that Cipla and Cipla USA have infringed the ’575 Patent, and a declaration that Cipla’s and Cipla USA’s commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the ’575 Patent;

H. A judgment that Cipla and Cipla USA have infringed the ’234 Patent, and a declaration that Cipla’s and Cipla USA’s commercial manufacture, use, marketing, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products would infringe the ’234 Patent;

I. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the Cipla ANDA No. 216787 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the Patents-in-Suit, including any extensions;

J. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining Cipla and Cipla USA, their respective officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of the Patents-in-Suit for the full terms thereof, including any extensions;

K. An order that damages or other monetary relief be awarded to Plaintiffs if Cipla or Cipla USA engages in the commercial manufacture, use, marketing, offer to sale, sale, and/or importation of the Proposed ANDA Products prior to the expiration of the Patents-in-Suit for the full terms thereof (including any extensions), and that such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment interest;

L. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

M. Costs and expenses incurred by Plaintiffs in this action; and

N. Such other and further relief as the Court may deem just and proper.

Dated: July 13, 2022

/s/ *Robert D. Rhoad*

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